Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Protocol summary

Summary

Nowadays, people show an increasing interest in using natural products. In this study the effect of Diabetan pill that is a blend of Saliva officinalis, Trigonella foenum and Ginseng will be investigated on blood glucose of diabetic patients. Methods: In a double-blind clinical trial 80 diabetic patients referred to endocrine and metabolism clinic in Shahrekord (Iran) will be selected and randomly designated into two groups of case and control. The case group will receive Diabetan and the control group will receive placebo tablets three times a day for three months. Glycosylated hemoglobin, lipid profile, fasting blood sugar (FBS) and 2 hours postprandial (2hpp) will be measured at the beginning and every 2 weeks, for three months. Hepatic enzymes will also evaluated and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011112696N2**
Registration date: **2010-12-18, 1389/09/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-18, 1389/09/27

Registrant information

Name

Mahmoud Rafieian-kopaei

Name of organization / entity

Shaharekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

rafieian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gol Daru Company

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Public title

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-Having type 2 diabetes based on internal criteria with FBS=126 or more and blood glucose 200 or more in daytime. 2- HbA1C more than 7% and less than 9% 3-Not having side effects of DM 4-Non-insulin dependent 5-Willing to participate in the trial 6-Not having a crucial illness 7- psychologically normal 8-Not using any other drugs for other diseases. Excluding Criteria: 1- Hyperglycemia with HbA1C more than 250 2-2hpp more than 9% and less than 7% 3-Pragnancy and lactation 4- Using insulin 5- Not willing to enter the trial 6- Having side effects of DM 7- Cardiovascular, hepatic, renal and other major systemic diseases 8-

psychologically abnormal 9- Using drugs for other illnesses 10- Type 1 DM 11- Age less than 30 years

Age
From **30 years** old to **149 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitee of Shahrekord University of Medical Sciences

Street address
Shahrekord, kashani St, Shahrekord University of Medical Sciences

City
Shahrekord

Postal code

Approval date
2010-04-11, 1389/01/22

Ethics committee reference number
87-11-2

Health conditions studied

1

Description of health condition studied
Diabetes Melitus (DM)

ICD-10 code
E10, E11,

ICD-10 code description
Diabetes Melitus

Primary outcomes

1

Description
HbA1C

Timepoint
At the beginning and at the end of trial (in 3 months

Method of measurement
Laboratory mg/ dl

2

Description
Lipid profile

Timepoint
At the beginning and end of the trial (in 3 months)

Method of measurement
mg/dl through lab methods

3

Description
Liver and kidney parameters

Timepoint
At the beginning and end of the trial (in 3 months)

Method of measurement
mg/dl through lab methods

4

Description
FBS and HbA1C

Timepoint
at the beginning of trial and every 2 weeks

Method of measurement
mg/dl

Secondary outcomes

empty

Intervention groups

1

Description
Diabetan tablet will be prescribed for them 3 times per day for three months

Category
Treatment - Drugs

2

Description
Placebo tablet will be prescribed 3 times per day for three months.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Metabolism clinic of Shahrekord University of Medical Sciences
Full name of responsible person
Mohamad Saeed Behradmanesh
Street address
Metabolism clinic of Shahrekord University of Medical Sciences
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gol Daru Co.
Full name of responsible person
Dr Falamarzian
Street address
Isfahan-Sofeh Shahrak-Gol Daru
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gol Daru Co.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty